510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 10/29/2013

1. Applicant / Submitter:

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DEC 0 4 2013

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
1515 E. Katella Ave. Unit 2115,
Anaheim, CA 92805
Phone: 714-202-5789 Fax: 714-409-3357
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3. Device:

Proprietary Name:	S Health
Common Name:	Healthcare Data Management Mobile Application
Classification Name:	Transmitters And Receivers, Physiological Signal, Radiofrequency System, Measurement, Blood-Pressure, Non-Invasive System, Test, Blood Glucose, Over The Counter Scale, Stand-On, Patient
Classification:	Class II, 21 CFR 870.2910 21 CFR 870.1130 21 CFR 862.1345 21 CFR 880.2700
Classification Product Code:	DRG, DXN, NBW, FRI

4. Predicate Device:

MedApps 2.0 – Remote Patient Monitoring System (K083862) by MedApps, Inc.
Ambio Remote Health Monitoring System (K130676) by Arrayent Health LLC /dba Ambio Health
Apps-Health01 (K122098) by Andon Health Co., Ltd.
iBGStar Diabetes Manager Application (K130535) by AgaMatrix, Inc.

5. Device Description:

The S Health is application software for mobile device. This mobile application helps users to care their personal health better by recording and displaying information such as comfort level(temperature and humidity), step count (pedometer), how much user exercises (calories burnt), the food user may consume (calories intake), weight, blood glucose level, and blood pressure in an effective and user friendly interface.

6. Intended Use:

The S Health is a mobile application intended for use in home to help people in reviewing and monitoring vital signs such as non-invasive blood pressure, blood glucose, weight and other data from optional add-on devices for effective health management. The user also can share the data via sharing functions (Email and SMS).

7. Performance Data(Non-Clinical):

Samsung Electronics Co, Ltd. conducted bench testing to demonstrate data accuracy transmission for each meter. Memory data rollover was also tested by adding ten (10) data points to meters that were pre-loaded with full memory. Test results show that all the measurement values, data, and time properly downloaded from the meters to the software. Memory data rollover also functioned properly where the new measurement values replaced the oldest glucose values.

In addition, a study intended to assess lay users' performance in using the S Health was conducted. Overall, they rated the S Health at 100% for overall program as easy or somewhat easy. There were no users that rated the software program as somewhat difficult or difficult. 100% of them also responded that they are satisfied with the S Health and its manual.

The study results supports that the S Health is effective and provides accurate data management system as other predicate devices in the market.

8. Substantial Equivalence

The predicate devices and S Health are optional software accessories for use with blood glucose, blood pressure, and weight with data management capability.
There are some minor differences between the subject device and the predicate device in software operation options, settings and some other features, but it does not constitute a new intended use. Despite the differences, the validation testing results presented in this 510K supports that the S Health is safe and effective as the predicate devices.

9. Conclusion:

Based on the testing results, Samsung Electronics concludes that the S Health is safe and effective also, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 4, 2013

Samsung Electronic Con. Ltd.
% Priscilla Chung
Official Correspondent
LK Consulting Group
1515 E Katella Ave. Unit 2115
Anaheim, CA 92805 US

Re: K132148
Trade/Device Name: S Health
Regulation Number: 21 CFR 870.2910
Regulation Name: Healthcare Data Management Mobile Application
Regulatory Class: Class II
Product Code: DRG, NBW, DXN, FRI
Dated: November 4, 2013
Received: November 7, 2013

Dear Priscilla Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K _____

Device Name: S Health

Indication for use:

The S Health is a mobile application intended for use in home to help people in reviewing and monitoring vital signs such as non-invasive blood pressure, blood glucose, weight and other data from optional add-on devices for effective health management. The user also can share the data via sharing functions (Email and SMS).

Prescription Use_____ AND/OR Over-The-Counter Use_✓_
(Part 21CFR801 Subpart D) (Part 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)